

**IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE**

In re Sitagliptin Phosphate ('708 & '921) Patent Litigation	C.A. No. 19-md-2902-RGA
<p>MERCK SHARP &amp; DOHME CORP.,</p> <p style="text-align: center;"><i>Plaintiff,</i></p> <p style="text-align: center;">v.</p> <p>AJANTA PHARMA LIMITED, and AJANTA PHARMA USA INC.,</p> <p style="text-align: center;"><i>Defendants.</i></p>	C.A. No. 20-1496-RGA

**SCHEDULING ORDER**

This 28 day of December, 2020, the parties having waived an initial Rule 16(b) scheduling conference pursuant to Local Rule 16.1(b),<sup>1</sup> and the parties having determined after

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<sup>1</sup> This Order follows substantially similar scheduling orders in the following related actions involving the same products and patents: (1) Order dated September 2, 2020, in related action C.A. No. 20-815-RGA; (2) Order dated June 28, 2019, in related actions C.A. Nos. 19-310-RGA, 19-311-RGA, 19-312-RGA, 19-313-RGA, 19-314-RGA, 19-316-RGA, 19-317-RGA, 19-318-RGA, 19-319-RGA, 19-320-RGA, 19-321-RGA, and 19-347-RGA; (3) Order dated August 21, 2019, in related action C.A. 19-872-RGA; (4) Order dated August 23, 2019, in related action C.A. No. 19-1489-RGA; (5) Order dated January 27, 2020, in related action C.A. No. 19-2192-RGA; (6) Order dated July 17, 2020, in related action C.A. 20-776-RGA; and (7) Order dated July 27, 2020, in related action C.A. 20-749-RGA. The parties have agreed that substantially the same schedule in the related actions should apply in this action. This Order thus provides for substantially similar due dates as the scheduling orders in the related actions, but has been edited to account for due dates that have already passed.

Additionally, on August 8, 2019, the Judicial Panel on Multidistrict Litigation ordered the centralization of many of the related actions and *Merck Sharp & Dohme Corp. v. Mylan Pharmaceuticals Inc. et al.*, Case No. 19-cv-101-IMK (N.D. W. Va.), to the U.S. District Court for the District of Delaware for coordinated and consolidated proceedings. *See* Transfer Order,

discussion that the matter cannot be resolved at this juncture by settlement, voluntary mediation, or binding arbitration;

IT IS ORDERED that:

1. Rule 26(a)(1) Initial Disclosures. The parties have agreed to exchange their initial disclosures pursuant to Federal Rule of Civil Procedure 26(a)(1) and Paragraph 3 of the Delaware Default Standard for Discovery on or before January 8, 2021.

2. Joinder of Other Parties and Amendment of Pleadings. All motions to join other parties, and to amend or supplement the pleadings, shall be filed on or before March 12, 2021.

3. Discovery.

a. Fact Discovery Cut Off. All fact discovery in this case shall be initiated so that it will be completed on or before March 12, 2021.

b. Document Production. Document production shall be substantially complete by February 19, 2021.

c. Contentions. The parties shall make their initial disclosures under Paragraphs 3 and 4 in accordance with the Court's Default Standard for Discovery, Including Discovery of Electronically Stored Information ("the Default Standard").

i. Merck Sharp & Dohme Corp. ("Plaintiff") shall make its disclosures under Paragraph 4(a) of the Default Standard by December 30, 2020.

ii. Ajanta Pharma Limited and Ajanta Pharma USA Inc. ("Defendant") shall produce its core technical documents under Paragraph 4(b) of the Default Standard by December 30, 2020. At the same time Defendant produces its

core technical documents, Defendant shall also produce the DMF for the sitagliptin API used in its proposed ANDA products, to the extent it is in Defendant's possession, custody, or control, or if Defendant able to obtain the DMF pursuant to a contractual right to the DMF with the DMF holder. If Defendant not in possession, custody, or control of the DMF, and is not able to obtain the DMF pursuant to a contractual right with the DMF holder, the Defendant shall inform Plaintiff of that fact and identify the DMF holder at the same time it produces their core technical documents.

- iii. Plaintiff shall make its disclosure under Paragraph 4(c) of the Default Standard by January 29, 2021;
- iv. Defendant shall make its disclosures under Paragraph 4(d) of the Default Standard by December 30, 2020.
- v. Plaintiff shall provide its supplemental infringement contentions on March 12, 2021.
- vi. Defendant shall provide its supplemental invalidity contentions on January 15, 2021.

d. Samples. By January 14, 2021, Defendant shall disclose to Plaintiff whether it is able to produce reasonable quantities of unexpired samples (as of the entry of this Scheduling Order) of its ANDA products and API to the extent such samples are in Defendant's possession, custody, or control, or if Defendant can obtain such samples pursuant to a contractual right with a supplier. On or before February 1, 2021, Defendant shall produce reasonable quantities of unexpired samples (unexpired as of the entry of this Scheduling Order) of the ANDA products and API to the extent such samples are in Defendant's possession, custody, or control, or if

Defendant can obtain such samples due to a contractual right with a supplier. For clarity, if Defendant does not have unexpired samples (unexpired as of the entry of this Scheduling Order) of their ANDA Product and API in their possession, custody, or control, and cannot obtain such samples pursuant to a contractual right with a supplier, Defendant shall inform Plaintiff of those facts at the same time it produces its core technical documents.

e. Requests for Admission. Plaintiff may serve up to **15** requests for admission on the Defendant Groups collectively.<sup>2</sup> To the extent that a request for admission is served on the Defendant Groups collectively, that request for admission shall count as one request for admission even if multiple parties provide a distinct response. The Defendant Groups collectively may jointly serve up to **15** requests for admission on Plaintiff. In addition, each Defendant Group may serve on Plaintiff up to **15** individualized requests for admission, and Plaintiff may serve on each Defendant Group up to **15** individualized requests for admission. Any additional requests for admission may only be served with leave of Court. Any requests for admission directed to the authentication of documents are excluded from the limitations above.

f. Interrogatories. Plaintiff may serve up to **15** interrogatories on the Defendant Groups collectively. To the extent that an interrogatory is served on the Defendant Groups

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<sup>2</sup> The Defendant Groups (in this action and the related actions) are: (1) Accord Healthcare, Inc.; (2) Ajanta Pharma Limited and Ajanta Pharma USA Inc.; (3) Alvogen Pine Brook LLC F/K/A Alvogen Pine Brook, Inc. and Alvogen Malta Operations Ltd.; (4) Anchen Pharmaceuticals, Inc. and Par Pharmaceutical, Inc.; (5) Apotex Inc. and Apotex Corp.; (6) Aurobindo Pharma Limited and Aurobindo Pharma USA, Inc.; (7) Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd.; (8) Lupin Limited and Lupin Pharmaceuticals, Inc.; (9) Macleods Pharmaceuticals Limited and Macleods Pharma USA, Inc.; (10) Mylan Pharmaceuticals, Inc.; (11) Sandoz Inc.; (12) Sun Pharma Global FZE and Sun Pharmaceutical Industries Ltd.; (13) Teva Pharmaceuticals USA, Inc.; (14) Torrent Pharmaceuticals Limited and Torrent Pharma Inc.; (15) Watson Laboratories, Inc. and Teva Pharmaceuticals USA, Inc.; (16) Wockhardt Bio AG and Wockhardt USA LLC; (17) Zydus Pharmaceuticals (USA) Inc. and Cadila Healthcare Ltd.; and (18) Unichem Laboratories Limited and Unichem Pharmaceuticals (USA), Inc.

collectively, that interrogatory shall count as one interrogatory even if multiple parties provide a distinct response. The Defendant Groups collectively may jointly serve up to **15** interrogatories on Plaintiff. In addition, each Defendant Group may serve on Plaintiff up to **10** individualized interrogatories, and Plaintiff may serve on each Defendant Group up to **10** individualized interrogatories. Any additional interrogatories may only be served with leave of Court.

g. Depositions.

i. Limitation on Hours for Deposition Discovery. Plaintiff is limited to 50 hours of taking fact deposition testimony upon oral examination per Defendant Group, including testimony of former Defendant Group employees.<sup>3</sup> The Defendant Groups collectively are limited to 130 hours of taking fact deposition testimony upon oral examination, including testimony of former Plaintiff employees. Any deposition lasting less than 5 hours will count as 5 hours against the total time of the side taking the deposition. These hour limits on fact depositions may be increased by Court order upon good cause shown. Depositions of inventors of the patents-in-suit who are designated as 30(b)(6) witnesses will be limited to 10 hours per inventor. Depositions of inventors of the patents-in-suit who are not designated as 30(b)(6) witnesses will be limited to 7 hours per inventor. Separate and apart from these hour limits on fact depositions, Plaintiff may depose each witness offered as an expert by a Defendant Group, and the Defendant Groups collectively may depose each witness offered as an expert by Plaintiff. If a deponent testifies wholly or substantially through an interpreter, the party taking the deposition shall be permitted, on a pro rata basis, two hours of deposition time for each hour

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<sup>3</sup> To the extent the same individual is deposed for more than one Defendant Group, there shall be a single deposition.

spent testifying through the interpreter. For clarity, the hour limitations described in this paragraph do not apply to depositions of third-parties or expert witnesses.

ii. Location of Depositions. The parties shall meet and confer regarding the locations of depositions, taking into account convenience for the deponent.

h. Discovery Matters and Disputes Relating to Protective Orders. Should counsel find they are unable to resolve a discovery matter or a dispute relating to a protective order, the parties involved in the discovery matter or protective order dispute shall contact the Court's Case Manager to schedule an in-person conference/argument. Unless otherwise ordered, by no later than seven business days prior to the conference/argument, any party seeking relief shall file with the Court a letter, not to exceed three pages, outlining the issues in dispute and its position on those issues. By no later than five business days prior to the conference/argument, any party opposing the application for relief may file a letter, not to exceed three pages, outlining that party's reasons for its opposition. A party should include with its letter a proposed order with a detailed issue-by-issue ruling such that, should the Court agree with the party on a particular issue, the Court could sign the proposed order as to that issue, and the opposing party would be able to understand what it needs to do, and by when, to comply with the Court's order. Any proposed order shall be e-mailed, in Word format, simultaneously with filing to rga\_civil@ded.uscourts.gov. Should any document(s) be filed under seal, a courtesy copy of the sealed document(s) must be provided to the Court within one hour of e-filing the document(s).

If a discovery-related motion is filed without leave of the Court, it will be denied without prejudice to the moving party's right to bring the dispute to the Court through the discovery matters procedures set forth in this Order.

4. Protective Order. Counsel agree to use the Protective Order entered by the Court in Case No. 19-md-2902-RGA, D.I. 9, which includes the following paragraph:

Other Proceedings: By entering this order and limiting the disclosure of information in this case, the Court does not intend to preclude another court from finding that information may be relevant and subject to disclosure in another case. Any person or party subject to this order who becomes subject to a motion to disclose another party's information designated as confidential pursuant to this order shall promptly notify that party of the motion so that the party may have an opportunity to appear and be heard on whether that information should be disclosed.

5. Papers Filed Under Seal. When filing papers under seal, counsel shall deliver to the Clerk the required number of copies as directed in paragraph 6. A redacted version of any sealed document shall be filed electronically within seven days of the filing of the sealed document.

6. Courtesy Copies. The parties shall provide to the Court two courtesy copies of all briefs and one courtesy copy of any other document filed in support of any briefs (i.e., appendices, exhibits, declarations, affidavits etc.). This provision also applies to papers filed under seal.

7. Claim Construction. The parties agree to adopt the constructions, as agreed upon or as construed by the Court, in Case No. 19-md-2902-RGA.

8. Disclosure of Expert Testimony.

a. Expert Reports. Plaintiff's initial Federal Rule 26(a)(2) disclosure of expert testimony is due on or before April 2, 2021. Defendant's initial Federal Rule 26(a)(2) disclosure of expert testimony is due on or before February 19, 2021. Plaintiff's responsive reports, including Plaintiff's expert reports regarding objective indicia of nonobviousness, are due on April 16, 2021. Defendants' responsive reports are due on or before May 14, 2021.

Plaintiff's reply expert reports are due on or before June 25, 2021. Defendant's reply expert reports are due on or before June 4, 2021. No other expert reports will be permitted without either the consent of all parties or leave of the Court. If any party believes that an expert report does not comply with the rules relating to timely disclosure or exceeds the scope of what is permitted in that expert report, the complaining party must notify the offending party within one week of the submission of the expert report. The parties are expected to promptly try to resolve any such disputes, and, when they cannot reasonably be resolved, use the Court's Discovery Dispute Procedure or the complaint will be waived. The parties shall advise of the dates and times of their experts' availability for deposition by June 25, 2021. Depositions of experts shall be completed on or before July 21, 2021.

b. Objections to Expert Testimony. To the extent any objection to expert testimony is made pursuant to the principles announced in *Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579 (1993), as incorporated in Federal Rule of Evidence 702, it shall be made by motion no later August 11, 2021, unless otherwise ordered by the Court.

9. Case Dispositive Motions. There being no issues triable to a jury in this case at this time, a party may only file a motion for summary judgment if that party first obtains permission from the Court to do so.

10. Applications by Motion. Except as otherwise specified herein, any application to the Court shall be by written motion. Any non-dispositive motion should contain the statement required by Local Rule 7.1.1.

11. Pretrial Conference. On September 10, 2021, the Court will hold a Rule 16(e) final pretrial conference in Court with counsel beginning at 9:00 a.m. The parties shall file a joint proposed final pretrial order in compliance with Local Rule 16.3(c) no later than 5 p.m. on



the fourth business day before the date of the final pretrial conference. Unless otherwise ordered by the Court, the parties shall comply with the timeframes set forth in Local Rule 16.3(d) for the preparation of the proposed joint final pretrial order.

12. Motions in Limine. Motions *in limine* shall be separately filed, with each motion containing all the argument described below in one filing for each motion. Any supporting documents in connection with a motion *in limine* shall be filed in one filing separate from the motion *in limine*. Each party shall be limited to three *in limine* requests, unless otherwise permitted by the Court. The *in limine* request and any response shall contain the authorities relied upon; each *in limine* request may be supported by a maximum of three pages of argument and may be opposed by a maximum of three pages of argument, and the party making the *in limine* request may add a maximum of one additional page in reply in support of its request. If more than one party is supporting or opposing an *in limine* request, such support or opposition shall be combined in a single three page submission (and, if the moving party, a single one page reply). No separate briefing shall be submitted on *in limine* requests, unless otherwise permitted by the Court.

13. Trial. This matter is scheduled for a 3-day bench trial on issues of invalidity. Trial will begin at 8:30 a.m. on October 4, 2021, with the subsequent trial days beginning at 8:30 a.m. The trial will be timed, as counsel will be allocated a total number of hours in which to present their respective cases. The parties shall provide the Court with a status report on the need for individual bench trials regarding infringement by January 8, 2021.

14. ADR Process. This matter is referred to a magistrate judge to explore the possibility of alternative dispute resolution.

15. Service By E-Mail. The parties consent to service by e-mail, in accordance with Rule 5(b)(2)(E) of the Federal Rules of Civil Procedure. The parties agree that service on any party by e-mail shall be made on both Delaware and Lead counsel for that party.

/s/ Richard G. Andrews

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**UNITED STATES DISTRICT JUDGE**